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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,652	04/30/2001	Akihiro Kondo	KONDO 7	1863

1444 7590 11/24/2003

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/24/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/830,652

Applicant(s)

KONDO ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 13) filed on June 12, 2003 has been entered.
2. Claims 1-12 are cancelled. New claims 13-14 are pending in this application.

Response to Arguments

3. Applicants' response to the office action (Paper No.13) is fully considered and deemed persuasive.
4. With reference to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants' amendment is fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment (Paper No. 13)
5. With reference to the rejection made in the previous office action under 35 USC 102(e) Applicants' arguments and amendment are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment, arguments and new grounds of rejection.
6. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicants' arguments are fully considered and found persuasive. The rejection is withdrawn herein in view of the amendment arguments and new grounds of rejection.

New Grounds of rejections

7. The disclosure is objected because of the following informalities:
 - (i) in claim 14, step (b) "to the" is misspelled as "tote". Correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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A. Claim 13 recites the limitation "the DNA array". There is insufficient antecedent basis for this limitation in the claim because step (f) does not recite a DNA array. Further Claim 13 recites "the series of genes identified in step (f)" lacks antecedent basis since the limitation (genes identified) is not present in the same step.

B. Claims 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-14 recite the term "may" in step (c), which is unclear and indefinite because it is not clear if this limitation is an actual positive step in the method or a is it a property of the probe. Therefore meets and bounds of the claims are unclear.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friend et al. (USPN. 6,165,709) in view of Stoughton et al. (USPN. 5,965,352).

Friend et al. teach a method of claims 13-14, for determining a test substance (drug) or endocrine disruptor activity, and screening for said drug target wherein Friend et al. teach that the method comprises

(a) exposing a cell to a test substance (see column 3, lines 44-50);

(b) isolating a first mRNA from the cell that has been exposed to the test substance and a second mRNA from a cell that has not been exposed to the test substance (see column 3, lines 48-51);

(c) hybridizing the first mRNA and the second mRNA with a first and second probe, wherein said probes were made from said RNA species (see column 3, lines 44-56);

(d and e) comparing signal intensities (gene expression levels) observed using a first probe signal intensities with the second probe signal intensities and identifying a series of genes in which expression levels are altered as a result of exposure of the cell to the test substance (see column 3, lines 56-67, column 4, lines 1-13, column 63, lines 54-67, column 64, lines 1-17, column 11, lines 31-53, column 28, lines 3-15);

(f) determining changes in the cell transcriptional state influenced by the said test substance, wherein the transcriptional state involves genes on a DNA array comprise most or almost all of the genes of the genome of the said cell or organism (see column 27, lines 59-67, column 28, lines 3-15)

However Friend et al. did not specifically teach determining signal transduction pathway genes.

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Stoughton et al. teach a method for identifying signal transduction pathway genes (see column 11, lines 10-36, column 3, lines 58-67, column 4, lines 1-13, column 8, lines 13-33) wherein Stoughton et al. teach that the method comprises genes on a DNA array involve genes in kinase pathway, T cell receptor pathway, T- cell signaling pathway (see column 35, lines 50-66) and genes relevant to the action of a drug of interest in a biological pathway (see column 45, lines 16-37).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a method of screening for drug targets as taught by Friend et al. with a method of identifying a signal transduction pathway as taught by Stoughton et al. to achieve expected advantage of developing a an improved and sensitive molecular diagnostic method for drug targeting because Stoughton et al. taught that “the necessity to improve (faster and less expensive) the methods for characterizing drug activities, and cellular pathways affected by drugs based on effective interpretation of such data as gene expression data (see column 2, lines 39-47) . An ordinary practitioner would have been motivated to modify the method of screening for drug targets as taught by Friend et al. with the incorporation of the determining drug influenced signal transduction pathway as taught by Stoughton et al., which would improve the characterization of drug activity and facilitate in a better screening of drugs targeted to a specific biological pathway.

Conclusion


No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-305-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
November 18, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER